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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,071

05/31/2006

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EXAMINER

YEAGER, RAYMOND P

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,071	Applicant(s) MARUNAKA ET AL.	
	Examiner RAYMOND P. YEAGER	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 11-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/31/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 to 21 are pending.

Election/Restriction

Applicant's election with traverse of group I, claims 1 to 10 in the reply filed on 06/16/2009 is acknowledged. The traversal is on the ground(s) that there is no search burden. This is not found persuasive because search burden is not a criteria for restriction in US National Stage entry per 35 USC 371 application; restriction is guided by PCT rule 13.2.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11 to 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/16/2009.

Priority

Application 10/581,071 (05/31/2006) is a national stage entry of PCTUS PCT/JP04/18112 (11/30/2004) per 35 USC 371 and claims foreign priority to JAPAN 2003-401691 (12/01/2003) per 35 USC 119. Foreign priority has not been perfected as a certified translation of the foreign document has not been provided. As such the pending claims 1 to 10 are considered to have a priority date of 11/30/2004.

Information Disclosure Statement

The Information Disclosure Statement (1) has been reviewed. Applicants are reminded of their duty to disclose all information known to them to be material to patentability as defined in 37 CFR 1.56.

Note – Specification

The use of the trademarks has been noted within this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- Claims 1 to 4 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 3,751,277 (Publication date: 08/07/1973), hereafter referred to as the '277 patent.

Applicant claims method for improving printability or abrasion resistance of a print to be produced on a surface of a solid dosage form, which comprises treating said surface with a polyethylene glycol (PEG)-containing aqueous solution before printing wherein the PEG has a molecular weight from 3,000 to 9,000 and is present at about 0.01 to about 1.0 percent of the film-coated tablet. The applicant also claims a method for producing a solid dosage form with a printed surface.

The '277 patent discloses a method of applying a coating solution to tablets (i.e. solid dosage formulations; columns 5, line 68 to column 6, line 8 and column 7-8, example 3) (limitations in instant claims 1). The composition for coating comprises polyethylene glycol (cover page, abstract). The '277 patent claims a PEG molecular weight from 5,500 to 8,000 which anticipates the instantly claimed PEG molecular weight (limitations in instant claims 2 and 3). The '277 patent also provides for 7 to 22 percent PEG in the coating wherein the coating is 10 to 50 percent of an aqueous

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solution ('277, column 10, claim 8) with a value of 0.07 percent PEG (limitations in instant claims 4). The claim to "*for improving printability or abrasion resistance of a print to be produced on a surface of a solid dosage form*" is considered an inherent property per MPEP § 2112. Further, the '277 patent discloses the method is directed toward providing an improved coating to protect from abrasion ('277, column 1, lines 45-51) which is considered to perform the same function.

- Claims 1 to 3 and 6 to 8 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 541388118 (Publication date: 10/26/1979), hereafter referred to as the '118 publication, as evidenced by the English abstract.

Applicant claims method for improving printability or abrasion resistance of a print to be produced on a surface of a solid dosage form, which comprises treating said surface with a polyethylene glycol (PEG)-containing aqueous solution before printing wherein the PEG has a molecular weight from 3,000 to 9,000 and is present at about 0.01 to about 1.0 percent of the film-coated tablet. The applicant also claims a method for producing a solid dosage form with a printed surface.

The '118 publication teaches spraying tablets with PEG 6000 followed by printing (i.e printing occurs after the PEG coating is applied) ('118, abstract) (limitations in instant claims 1 to 3 and 6 to 8). The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. In the instant application the applicant claims an improvement in printability or abrasion resistance. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise. The phrase "*before printing*" is considered an intended use as no printing step is recited. As such "*before printing*" is not afforded patentable weight.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- Claims 1 to 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 541388118 (Publication date: 10/26/1979), hereafter referred to as the '118 publication, in view of US Patent 3,751,277 (Publication date: 08/07/1973), hereafter referred to as the '277 patent and WO 0057838 (Publication date: 10/05/2000), hereafter referred to as the '838 publication.

Applicant claims method for improving printability or abrasion resistance of a print to be produced on a surface of a solid dosage form, which comprises treating said surface with a polyethylene glycol (PEG)-containing aqueous solution before printing wherein the PEG has a molecular weight from 3,000 to 9,000 and is present at about 0.01 to about 1.0 percent of the film-coated tablet. The applicant also claims a method for producing a solid dosage form with a printed surface.

Determination of the scope and content of the prior art - (MPEP 2141.01)

The '118 publication teaches a method of spraying tablets with PEG 6000 followed by printing as discussed *supra*.

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between the instant application and the '118 publication is that '118 publication patent does not expressly teach applying a PEG coating to a film-coated tablet. This deficiency in '118 publication is cured by the teachings of the '277 patent and the '838 publication. The '277 patent discloses a method of applying a coating solution to tablets wherein the composition for coating comprises about 0.7 percent PEG with a MW from 5,500 to 8,000 (limitations of instant claims 1 to 4 and 6 to 9). The '838 publication teaches the application of a PEG 8000 (total at 0.25 percent weight) applied to a tablet with a film-coating ('838, pages 6-7, example 1 and table 1) (limitations in claims 5 and 10).

Finding of prima facie obviousness - Rational and Motivation - (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to improve abrasion resistance by applying a PEG coating as taught by the '277 patent and provide a film-coated solid dosage form as taught in the '838 publication.

One of ordinary skill in the art would have been motivated to do this because the '277 patent teaches a method directed toward providing an improved coating to protect from abrasion ('277, column 1, lines 45-51) and the '838 publication teaches applying the polish coat (i.e. PEG) to mask the taste and appearance qualities of a film-coated tablet (i.e. such as a tablet with HPMC) ('838, page 1, line 22 to page 2, line 5). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Relevant Prior Art Cited

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- US patent 6,254,888 teaches a process of providing a coating covering a brand on a pharmaceutical dosage form comprising a coating of water and PEG 8,000 at 0.5 to 5.0 percent ('888, abstract, column 3, line 58; and column 2, line 60 to column 3, lines 17).
- Rangaiah, et al 1997 (*Drug Development and Industrial Pharmacy*, vol. 23;4:419-423) teaches polishing of a tablet with 0.1 percent PEG 6000 (page 422, column 1, paragraph 3 to column 2, paragraph 2).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND P. YEAGER whose telephone number is (571) 270-7681. The examiner can normally be reached on Mon - Thurs 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.P.Y.

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